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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Ronald A. Schachar
Serial No.:	09/556,143
Filed:	April 21, 2000
Title:	SEGMENTED SCLERAL BAND FOR TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS
Art Group Unit:	3769
Examiner:	David M. Shay
Confirmation No.:	6710

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. § 41.41

This Appellant's Reply Brief Under 37 C.F.R. § 41.41 ("Reply Brief") is filed in response to the Examiner's Answer, which was mailed on February 18, 2009. The deadline for filing this Reply Brief is April 18, 2009, so this Reply Brief is timely filed.

ARGUMENTS IN RESPONSE TO THE EXAMINER'S ANSWER

This Reply Brief incorporates all prior arguments set forth in the Appellant's Appeal Brief filed on October 20, 2008, including all arguments for claims not specifically addressed below.

Definition of "Comprising" Is Well Established

Claims 40, 47, and 54 recite irradiating a sclera of an eye by "reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera."

The Examiner's Answer states that the Appellant has "chosen to file comprising-type (i.e. open ended) claims," so these claims encompass "processes which ultimately produce a full scleral perforation." (*Examiner's Answer, Page 5, Second paragraph*).

This, of course, is improper and contradicts the long-settled definition of the term "comprising." As noted in MPEP § 2111.03, the term comprising "does not exclude additional, unrecited elements or method steps." In other words, the term "comprising" allows for other elements in addition to those elements expressly recited in a claim. The term "comprising" does not mean "in contradiction to" those elements expressly recited in a claim.

Claims 40, 47, and 54 all clearly recite reducing a thickness of the sclera of an eye in a particular region "without forming an opening completely through the sclera." The Examiner cannot ignore these elements of these claims on the basis that the claims use the transitional phrase "comprising."

Inherency Arguments Regarding the Disclosure of March

The Examiner's Answer incorporates and repeats many of the same arguments previously made regarding the alleged inherent teachings of *March*. (See *Examiner's Answer, Pages 6-7*). Many of the Examiner arguments are reproduced below, along with the Appellant's comments.

Continuing, applicant asserts that the examiner has provided no fact or technical reasoning to support the determination of inherency. The examiner firstly notes, that the disclosures of the prior art are to be read in light of the knowledge of one of ordinary skill in the art. Given that one of ordinary skill in the art must at the very minimum be a[n] ophthalmological surgeon, and therefore, have not only completed college with at least one course in physics and chemistry, but gone to a minimum of 3 years of medical school and interned for a period of time after that, one having ordinary skill must be recognized as being a highly educated surgeon. (*Examiner's Answer, Page 6, Last paragraph*).

The Appellant agrees that a person skilled in the art would likely be highly educated, particularly given that the claimed subject matter deals with surgical procedures. However, this does not mean that the Examiner can make unfounded or unsupported assertions regarding the teachings of the cited art. The highly-skilled nature of the art is no substitute for actual evidence of inherency.

The Examiner continues by stating:

Given this level of education, the examiner respectfully submits that one of ordinary skill in the art would recognize that removing tissue from a structure such as the sclera must necessarily weaken the sclera. (*Examiner's Answer, Page 6, Last paragraph*).

Note how the Examiner gives no proof that the removal of any scleral tissue in any manner whatsoever would weaken the sclera and allow for scleral expansion. The Examiner simply

makes the assertion that other people would agree with the Examiner. If the Appellant made this type of statement, the Examiner would likely reject such as statement as merely unsupported argument. The same is true for the Examiner's arguments of inherency. The Examiner's argument here basically amounts to an unsupported assertion that "highly educated people agree with me." This is not evidence of inherency.

The Examiner then states:

The examiner is unaware of any process, material, or theory that affords or asserts the ability of strengthening a structure, or even allowing the structure to remain at the same strength, while removing some of the material that constitutes this structure. If applicant is aware of any such disclosure, the examiner would be most interested to review it. (*Examiner's Answer, Page 6, Last paragraph*).

Here the Examiner engages in improper burden-shifting. Unable to present any actual evidence that the treatment of *March* would inherently weaken the sclera and cause scleral expansion, the Examiner places the burden of disproving the Examiner's assertions onto the Appellant. This, of course, is improper. The burden of establishing inherency is placed on the Examiner. (*MPEP* § 2112). Having never proven that "any material removed from any part of an eye in any way weakens the eye and allows scleral expansion and an increase in the ciliary muscle's effective working distance," the Examiner cannot shift the burden of disproving his unproven assertions onto the Appellant.

The Examiner continues by stating:

Absent any such showing, however, the examiner must rely upon the laws of physics as they are currently understood and presume that removal of the substance of a structure will leave that structure

weaker than before the removal. (*Examiner's Answer, Page 6, Last paragraph*) (emphasis added).

Multiple times, the Appellant has requested that the Examiner identify these unnamed "laws of physics." Multiple times, the Examiner has failed to identify the "laws of physics" that are relied upon in rejecting the claims. As a result, this is just another unsupported assertion made by the Examiner in attempting to make an inherency argument. Most telling is the Examiner's use of the word "presume" here. It is well-established that the burden is on the Examiner to present evidence clearly showing that "the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." (*MPEP § 2112*). Mere "possibilities" (or "presumptions") are inadequate for establishing inherency. In addition, the Examiner has never established that "any material removed from any part of an eye in any way weakens the eye and allows scleral expansion and an increase in the ciliary muscle's effective working distance." That is what is relevant to the claims at issue here, not whether any generic structure is somehow weakened by some unspecified removal of material.

The Examiner concludes by stating:

Given that the structure is weaker, this necessarily requires that the structure will expand due to the internal pressure thereof in combination with [its] weakened state. This expansion will also necessarily cause the effective working distance of the ciliary muscle to increase given that the ciliary muscle joins the iris to the sclera... Thus the examiner must respectfully submit that one of ordinary skill in the art would immediately recognize that the intended results recited in the claimed would, at least to a small degree, be produced by the procedure of March et al.

Here, the Examiner assumes that the removal of tissue from the eye as taught by *March* weakens the eye, assumes that this weakening allows the sclera to expand, and assumes that this expansion increases the effective working distance of the ciliary muscle of the eye. Of course, the Examiner ignores the express stated purpose of *March* in making this series of assumptions.

March is directed at forming complete scleral perforations through the eye in order to treat glaucoma. The idea in *March* is that the scleral perforations can be used to lower intraocular pressure within the eye, thus treating glaucoma (which is a condition marked by elevated pressure within the eye). (See *March*, Page 584, Introduction). If anything, the lowering of intraocular pressure as taught by *March* would decrease the size of the eye due to the eye's lower internal pressure, not increase the size of the eye. In effect, the Examiner's assumptions are based on the argument that poking a hole in a balloon allows the balloon to expand in size, even as the pressure inside the balloon is decreasing.

The burden is placed on the Examiner to provide evidence why *March* inherently discloses the Appellant's invention as recited in Claims 40, 47, and 54 (and their dependent claims). The Examiner's unsupported and unsubstantiated assertions fail to satisfy this burden. Despite the Examiner's assertions regarding the "laws of physics" as understood by the Examiner, the Examiner has never identified what those laws of physics are. More importantly, the Examiner has never shown that any "anatomical laws" require that any removal of tissue from the eye allows for scleral expansion and an increase in the effective working distance of the ciliary muscle of the eye. As a result, the Examiner has failed to satisfy the burden placed on the Examiner in establishing inherency.

“Prior Art” Techniques from *March* are Complete Unknowns

As noted previously by the Appellant, *March* mentions various “previous laser treatments for glaucoma” and describes a “new” or “improved” laser treatment that forms a complete scleral perforation. The Appellant noted in the Appeal Brief that the “previous laser treatments” in *March* failed to create a “complete scleral perforation.” The Appellant also noted in the Appeal Brief that *March* fails to describe those “previous laser treatments” in any way. *March* never discloses the exact locations of laser irradiation in the previous laser treatments, the amount of tissue removed during those previous laser treatments, or any other details of those previous laser treatments. The Examiner’s Answer asserts that *March* “does not in any way imply that the previous techniques were intended to create a sclerostomy.” (*Examiner’s Answer, Page 4, First paragraph*). The Appellant notes that *March* appears to equate a sclerostomy with a scleral perforation, which is consistent with the standard medical definition of “sclerostomy.”

So in addition to never disclosing any details of those previous laser treatments, the Examiner now acknowledges that the intent of the previous laser treatments described in *March* is also in question. With this admission, the Examiner can now only argue that *March* discloses “previous laser treatments” that involved some type of laser irradiation of an eye in some undescribed manner for some unstated purpose, which failed to produce a scleral perforation. On this the Examiner rests his arguments of inherency.

While the Examiner argues that the intent of the “previous laser treatments” is not relevant, the details of those “previous laser treatments” are relevant. The truth of the matter is that the Examiner and the Appellant both have no idea of what occurs during the “previous laser

treatments” of *March*.

As noted previously by the Appellant, there are only three possible arguments how *March* might anticipate the claims:

- (i) the “new” or “improved” procedure in *March* after completion anticipates the claims;
- (ii) the “new” or “improved” procedure in *March* at some point after initiation and prior to completion anticipates the claims; or
- (iii) the “previous laser treatments” described in *March* anticipate the claims.

Regarding (i), the “new” or “improved” procedure in *March* taken to completion forms a complete scleral perforation, which is expressly prohibited by the claims (even with the use of the term “comprising” in the claims). The “new” or “improved” procedure in *March* therefore cannot anticipate the claims.

Regarding (ii), *March* discloses using a pulsed laser with 12-nanosecond pulses, which are typically separated by extremely short periods of time. (*March*, Page 584, Right column). The Examiner has not and cannot establish that scleral weakening and scleral expansion occur during the extremely brief periods of time between the laser pulses of the “new” or “improved” procedure in *March*.

Regarding (iii), *March* is silent regarding practically all details regarding the “previous laser treatments.” Again, the Examiner has not and cannot establish that scleral weakening and scleral expansion occur as a result of the “previous laser treatments” discussed ever so briefly in *March*.

For these reasons, the Examiner fails to establish that *March* anticipates all clements recited in Claims 40, 47, and 54 (and their dependent claims). As a result, all pending claims are patentable over *March*.

Accordingly, the Appellant respectfully requests withdrawal of all outstanding rejections and full allowance of all pending claims.

The Appellant has demonstrated that the present invention as claimed is clearly distinguishable over the prior art cited of record. Therefore, the Appellant respectfully requests that the Board of Patent Appeals and Interferences reverse the final rejection of the Examiner and instruct the Examiner to issue a notice of allowance of all claims.

The Director is hereby authorized to charge any fees (including any extension of time fees) or credit any overpayments to Deposit Account No. 50-0208.

Respectfully submitted,

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